

REMARKS

Claims 1, 4-8, 11 and 12 are all the claims pending in the application. Claims 1, 4-8, 11 and 12 were rejected

Claims 1 and 8 have been amended to delete a recitation added by the previous amendment and to replace the “comprising” language with “consisting essentially of” language. Support is found throughout the specification. See, for example, page 5, lines 7-20.

Accordingly, no new matter is added.

Claim Rejection - 35 U.S.C. § 103(a)

In the Office Action, the rejection of claims 1, 4-8, 11 and 12 under 35 U.S.C. § 103(a) as being unpatentable over Ueda, et al. in view of Woo, et al. was maintained for reasons of record. The Examiner repeated the rejection previously issued, and did not address Applicants’ arguments from a substantive standpoint.

Accordingly, in the next communication, the Examiner is requested, respectfully, to address each of Applicants’ arguments with particularity.

Applicants again respectfully submit that the Examiner’s rational for the rejection is contrary to the law and internally inconsistent, and, that the combination of the reference teachings does not result in the present invention.

More specifically, in Applicants’ response to the previous Office Action, Applicants pointed out that there is no motivation to combine the references, because Woo is directed to a patch preparation specifically for use with non-steroidal anti-inflammatory drugs (NSAID), whereas Ueda discloses a patch preparation for use with a dihydropyridine compound, which is not an NSAID. Woo overcomes the prior art problems by formulating a composition that causes

the NSAID to be stably dissolved and diffused in an “almost microemulsion state.” On the other hand, the alleged novelty of Ueda’s composition is an absorption promoter, which is capable of promoting percutaneous absorption of the dihydropyridine compound. The two references are directed to solving entirely different problems and the problems are unique to the drug used.

Nonetheless, the Examiner maintained that the skilled artisan would readily substitute the composition of Woo for that of Ueda, stating only that “ample motivation is provided by the prior art to use the combined reference teachings to obtain an effective pharmaceutical composition for percutaneous drug absorption.” Office Action, page 6, first full paragraph. This is a mere assertion with no supporting rationale. The Examiner has not identified any specific motivation for combining the teachings.

Should the Examiner persist in this position, the Examiner is requested to explain what exactly constitutes the alleged “ample motivation.” For example, is the Examiner asserting that that the skilled artisan would arbitrarily combine components of different compositions for percutaneous drug absorption, regardless of the nature of the drug?

Furthermore, Applicants respectfully submit that the Examiner’s description of the patch of Ueda is internally inconsistent in order to try to force a teachings that is not there. Thus, in order to try to establish that the patch of Ueda discloses a support that has the claimed thickness of the support of applicant’s patch, the Examiner cites to the intermediate EVA film layer Ueda uses on top of the ointment. In the same sentence, however, the Examiner also refers to the aluminum support. Office Action, page 3, lines 12-14.

However, it is clear that the EVA film of Ueda is not a support. It is an intermediate film used to control the release of the absorption promoter. Ueda, Col. 4, lines 10-17. Thus, the

Examiner is incorrect in asserting that the EVA film is the equivalent of the presently claimed support, and, therefore it would be a matter of routine experimentation to adjust the EVA film to have the claimed physical characteristics of applicants' vinyl acetate and acrylic acid support.

Ueda has no teaching or suggestion to use EVA as a support material. Thus, those skilled in the art would not be motivated to manipulate the film to obtain the best possible results for a support, as asserted by the Examiner. Office Action, page 6, first full paragraph. That is, if the EVA film is not used as a support, one skilled in the art would not be motivated to manipulate it to be pliable, yet retain strength and be non-absorbent of the drug.

Additionally, even if the teachings of the references were combined, the present invention would not be achieved. Rather, the combination as described by the Examiner would result in a patch with an aluminum support and an ointment that contains polyvinyl acetate-acrylic acid copolymer, covered with an EVA film that controls the release of the absorption promoter.

This patch can in no way be said to comprise a pliable support that is composed of a copolymer of vinyl acetate and acrylic acid, wherein the copolymer is obtained by copolymerizing a vinyl acetate, an alkyl ester of a (meth)acrylic acid with the alkyl having 4 to 14 carbon atoms on average, and a (meth)acrylic acid in amounts of 0 to 90 wt%, 10 to 97 wt%, and 0 to 15 wt%, respectively, and the copolymer is cross-linked. Further, even if the EVA film were manipulated to have the recited modulus and water vapor permeability, the aluminum support of Ueda would not have these characteristics.

In this respect, one aspect of the present invention is to provide a patch that has a pliable support, yet wherein the ointment does not migrate into the support and wherein there is no change in the modulus of the support when the ointment is provided thereon. Such a support is

neither taught nor suggested by either of the cited references and, therefore, cannot be taught by the combination thereof.

Finally, the independent claims have been amended to use "consisting essentially of" language, thereby excluding intermediate layers, such as that taught by Ueda, and supports, such as the aluminum support taught by Ueda, that affect the essential characteristics of the invention. See specification, page 5, lines 7-20.

Accordingly, the Examiner is requested, respectfully, to reconsider and remove this rejection.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

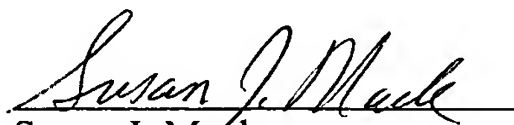
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